Special 510(k) Summary of Safety and Effectiveness: Modifications to the AVS™ PL PEEK Spacer System

APR 2 4 2009

Proprietary Name:	AVS™ PL PEEK Spacer System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class II
	Interevertebral body fusion device
	21 CFR 888.3080
Device Product Code:	MAX
For Information contact:	Vikki M. O'Connor Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8215 Fax: (201) 760-8415 Email: Vikki.O'Connor@Stryker.com
Date Summary Prepared:	March 18, 2009
Predicate Device	AVS™ PL PEEK Spacers (K073470, K080758 and K082014) DePuy AcroMed, Inc. Lumbar I/F Cage® with VSP Spine System: P960025 (i.e., Brantigan Cage)
Predicate Device Information	The subject AVS™ PL PEEK Spacers and the predicates AVS™ PL PEEK Spacers and DePuy's Lumbar I/F Cage (i.e., Brantigan Cage) share similar design features: • Hollow frame PEEK Implant • Lateral fenestrations • Serrations on the superior and inferior surfaces

- Comparable heights, widths, and angles
- Materials and mechanical testing results are similar between the subject device and the listed predicates.

Description of Device Modification

This Special 510(k) premarket notification is intended to introduce the following modifications to the AVS™ PL PEEK Spacers approved under K073470, K080758, and K082014:

A range of 0° and 4° AVS™ PL PEEK Spacers (6-13mm in height, 30 and 33mm lengths with an 11mm width) were found to be substantially equivalent to the Brantigan Cage in K073470. In K080758, minor design changes were introduced to the 0° degree spacers. K082014 added four (4) implants in a 14 mm height. The minor design modifications approved under K080758 had been incorporated in these 14 mm implants.

The AVS™ PL PEEK Spacers that are the subject of this application add the design modifications that were approved on the 0 ° implants under K080758, to the 4 ° implants previously approved under K073470 and K082014. The lengths, width, and angles are the same as the predicate AVS® PL PEEK Spacers previously approved. The modifications include replacing the ogival shaped nose of the implant with the wedge-shaped design to facilitate insertion of the spacer between adjacent vertebral endplates. The threaded hole on the front side was removed as it is not needed to retrieve the implant and field feedback has confirmed that it would likely not be used. In the smaller heights, the back side threaded hole has been adapted to the various heights of the spacers to remain consistent with the existing instruments (i.e., the two Inserters), and the back side of the spacer has been tapered in the frontal plane to match

	the geometry of the vertebral endplates and the size of the two flat surfaces has been increased to improve the connection with the Inserters. Note that the AVS™ PL PEEK Spacers may also be referred to as AVS™ Plus or UniLIF.
Intended Use	The Stryker Spine AVS™ PL PEEK Spacers are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. The AVS™ PL PEEK Spacers are to be implanted via posterior approach. The AVS™ PL PEEK Spacers are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).
Summary of the Technological Characteristics	Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the AVS PL PEEK Spacers and demonstrated substantially equivalent performance characteristics to the identified predicate device systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Corporation
% Ms. Vikki M. O'Connor
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

APR 24 2009

Re: K090816
Trade/Device Name: Stryker Spine AVS PL PEEK Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Product March 23, 2009
Received: March 25, 2009

Dear Ms. O'Connor:

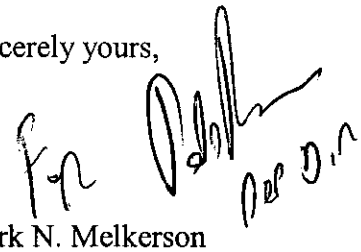
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090816

Device Name: Stryker Spine AVS PL PEEK Spacers

Indications For Use:

The Stryker Spine AVS PL PEEK Spacers are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The AVS PL PEEK Spacers are to be implanted via posterior approach.

The AVS PL PEEK Spacers are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090816